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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,670	05/07/2002	Dan L. Eaton	P3230R1C001-168	7260
30313	7590	09/13/2004	EXAMINER	
KNOBBE, MARTENS, OLSON & BEAR, LLP 2040 MAIN STREET IRVINE, CA 92614			NICKOL, GARY B.	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

10/063,670

### Applicant(s)

EATON ET AL.

### Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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Re: Eaton *et al.*

Date of priority: 10/29/1997

Claims 1-20 are pending.

### ***Specification***

The specification is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (i.e., see page 31). Applicant is required to delete all embedded hyperlinks and/or other forms of browser-executable code. See MPEP § 608.01.

### ***Claim Objections***

The claims are objected to for improper numbering, i.e. the numbers include the letter “c”. For example, the claims are numbered “c1 to c20”. Appropriate corrections are requested.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 19-20, as written, do not sufficiently distinguish over cells as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v.*

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*Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Claims 1-20 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

The claims are broadly drawn to isolated nucleic acids that have at least 80%, 85%, 90%, and/or 99% sequence similarity to SEQ ID NO:5 and or to nucleic acids encoding the amino acid sequence of SEQ ID NO:6 . The specification refers to this encoded amino acid protein as "PRO263" (page 11, para 31). The disclosure (page 139-140) further identifies PRO263 as having tested "positive" in stimulating the release of TNF- $\alpha$  in human blood. It is further noted that the disclosed utility for PRO263 (page 529, para 527) appears to be for "research purposes" where stimulation of the release of TNF- $\alpha$  would be desired and for the "therapeutic treatment" of conditions in which enhanced TNF- $\alpha$  would be beneficial. However, neither the specification nor any art of record teaches what PRO263 is, how it functions, or a specific and well-established utility for any of the claimed variants. Furthermore, the specification does not teach a relationship to any specific disease or establish any involvement in the etiology of any specific disease where TNF- $\alpha$  would be desired. On the contrary, it would appear that the majority of clinical research involving this cytokine is aimed at *blocking* the undesirable effects of TNF- $\alpha$ . For example, Paleolog E. (Expert Opin. Investig. Drugs, Vol. 12, No. 7, pp. 1087-1095, 2003) recently reviewed the therapeutic potential of blocking TNF- $\alpha$  in rheumatoid arthritis using monoclonal antibodies. Others have shown that TNF- $\alpha$  is an essential mediator in the formation of tumors. For example, through transgenic mice studies, Suganuma *et al.* (Cancer Res. Vol. 59, pages 4516-4518, September 1999) hypothesized that TNF- $\alpha$  is the key cytokine for tumor promotion in mouse skin and, very possibly, for carcinogenesis in humans. Thus, blocking the

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effects of TNF- $\alpha$  appears to be more clinically desirable. Again, the specification does not teach a relationship to any specific disease or establish any involvement in the etiology of any specific disease where TNF- $\alpha$  would be desired. There is little doubt that, after complete characterization, this nucleic acid, may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

Hence, the specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the disclosed nucleic acids and fragments thereof. Thus, because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility of any utility cannot be assessed.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to *use* the claimed invention.

Claims 1-5, and 14-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth SEQ ID NO:5 and or an isolated nucleic acid encoding SEQ ID NO:6 and therefore the written description is not commensurate in scope with the claims which read on allelic variants of SEQ ID NO. 5.

The claims are broadly drawn to nucleic acids having at least 80%, 85%, 90%, 95% or 99% sequence identity to SEQ ID NO:5, nucleic acids encoding SEQ ID NO:6. The claims are further drawn to nucleic acids that hybridize to SEQ ID NO:5 and or nucleic acids that hybridize to nucleic acids encoding SEQ ID NO:6. The claims do not require that these nucleic acids or



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encoded products possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a **genus** of polypeptides that is defined only by sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. Further, there is no identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Applicants should further refer to Example 9 of the revised interim Written Description Guidelines regarding appropriate hybridization language (see <http://www.uspto.gov/web/menu/written.pdf>).

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method

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of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required.

See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated nucleic acid comprising SEQ ID NO:5 and or an isolated nucleic acid encoding SEQ ID NO:6, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is indefinite for reciting "stringent conditions" as the specification does not contain a limited definition of what is defined by such conditions. The specification only teaches that which is considered exemplary stringent conditions (para 227). Thus, stringent conditions read on the full range of stringent conditions, that is from very permissive to very high



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stringency. Hence, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention and would not be able to determine the metes and bounds of the claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 14-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni *et al.*

(US Patent No. 5,942,417, July 1996).

Ni *et al.* teach an isolated nucleic acid molecule that is 96.6% identical to SEQ ID NO:5 (see attached sequence listing). Ni *et al.* further teach vectors comprising said nucleic acids for recombinant expression in host cells (columns 14-15) and methods of hybridization (column 9) wherein the product of the prior art would clearly hybridize under stringent conditions to the claimed SEQ ID NO:5.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835.

The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.  
Primary Examiner  
Art Unit 1642

GBN

  
**GARY NICKOL**  
**PRIMARY EXAMINER**